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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

Intra-Cellular Therapies, Inc., Plaintiff, v. Sandoz Inc., Defendant.	Civil Action No. 3:24-cv-08855 (MAS-JBD)

DEFENDANT SANDOZ INC.'S ANSWER TO
COMPLAINT FOR PATENT INFRINGEMENT

Defendant Sandoz Inc. ("Sandoz") hereby answers and asserts the following defenses to the Complaint brought by Plaintiff Intra-Cellular Therapies, Inc. ("Plaintiff") on August 29, 2024.

ANSWER TO COMPLAINT

Each of the paragraphs and section titles below corresponds to the same-numbered paragraphs and section titles in Plaintiff's Complaint, respectively. Sandoz denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or specifications that arguably follow from the admitted facts. Sandoz denies that Plaintiff is entitled to the relief requested or any other relief.

With respect to the allegations made in the Complaint, Sandoz states as follows:

Nature of the Action

Complaint ¶ 1: This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, that arises out of Sandoz's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of CAPLYTA® (lumateperone) capsules, 10.5 mg, 21 mg, and 42 mg, prior to the expiration of U.S. Patent Nos. 11,980,617 ("the '617 patent") and 12,070,459 ("the '459 patent") (collectively, the "Patents-in-Suit").

Response: Paragraph 1 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the Complaint purports to state a civil action for patent infringement of United States Patent Nos. 11,980,617 ("the '617 patent") and 12,070,459 ("the '459 patent"). These patents are referred to collectively herein as the "Patents-in-Suit." Sandoz further admits that the Complaint purports to relate to Sandoz's submission of Abbreviated New Drug Application ("ANDA") No. 218938 ("Sandoz's ANDA") to the United States Food and Drug Administration ("FDA"), seeking approval of its generic lumateperone capsules, 10.5 mg, 21 mg, and 42 mg ("Sandoz's ANDA Product"). Sandoz denies the remaining allegations of Paragraph 1.

Complaint ¶ 2: Sandoz notified Plaintiff by letter dated February 15, 2024 ("Sandoz's Notice Letter") that it had submitted to the FDA ANDA No. 218938 ("Sandoz's

ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic lumateperone capsules, 10.5 mg, 21 mg, and 42 mg, ("Sandoz's ANDA Product") prior to the expiration of U.S. Patent Nos. 8,648,077 ("the '077 patent"), 9,168,258 ("the '258 patent"), 9,199,995 ("the '995 patent"), 9,616,061 ("the '061 patent"), 9,956,227 ("the '227 patent"), 10,117,867 ("the '867 patent"), 10,464,938 ("the '938 patent"), 10,695,345 ("the '345 patent"), 10,960,009 ("the '009 patent"), 11,026,951 ("the '951 patent"), 11,052,084 ("the '084 patent"), 11,690,842 ("the '842 patent"), 11,753,419 ("the '419 patent"), 11,806,348 ("the '348 patent"), RE48,825 ("the RE '825 patent"), and RE48,839 ("the RE '839 patent").

Response: Sandoz admits that it sent a letter, dated February 15, 2024, to Plaintiff ("Sandoz's Notice Letter") and states that Sandoz's Notice Letter speaks for itself. Sandoz further states that it submitted Sandoz's ANDA to the FDA seeking approval of Sandoz's ANDA Product. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 2.

Complaint ¶ 3: On March 28, 2024, Plaintiff sued Sandoz in this district for infringement of the patents identified in Sandoz's Notice Letter. *See* Civil Action No. 3:24-cv-04327-MAS-JBD, ECF No. 1. That case is currently pending and has been consolidated with Civil Action No. 3:24-cv-04264. ECF No. 22.

Response: Paragraph 3 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that Plaintiff filed a complaint alleging patent infringement against Sandoz on March 28, 2024 in Civil Action No. 3:24-cv-04327-MAS-JBD. Sandoz further admits Civil Action No. 3:24-cv-04327 is currently pending and has been consolidated with Civil Action No. 3:24-cv-04264.

The Parties

Complaint ¶ 4: Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 5: Plaintiff Intra-Cellular Therapies ("ITCI") is a corporation organized and existing under the laws of Delaware and having a place of business at 430 East 29th Street, Suite 900, New York, NY 10016. ITCI is the holder of New Drug Application ("NDA") No. 209500 for the manufacture and sale of lumateperone capsules, 10.5 mg, 21 mg, and 42 mg, which have been approved by the FDA.

Response: Sandoz admits that FDA's Orange Book identifies "INTRA-CELLULAR THERAPIES INC" as holder of NDA No. 209500 for the manufacture and sale of lumateperone capsules, 10.5 mg, 21 mg, and 42 mg, which have been approved by the FDA. Sandoz lacks sufficient knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 5 and therefore denies them.

Complaint ¶ 6: Upon information and belief, Defendant Sandoz is a corporation organized and existing under the laws of Delaware and having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

Response: Admitted.

Complaint ¶ 7: Upon information and belief, Sandoz is in the business of, among other things, importing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Sandoz knows and intends that upon approval of Sandoz's ANDA, Sandoz will manufacture Sandoz's ANDA Product and Sandoz will directly or indirectly market, sell, and distribute Sandoz's ANDA Product throughout the United States, including in New Jersey.

Response: Sandoz admits that it submitted Sandoz's ANDA to the FDA seeking approval of Sandoz's ANDA Product. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 7.

Jurisdiction

Complaint ¶ 8: Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 9: Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

Response: Paragraph 9 states legal conclusions to which no response is required. To the extent that a response is required, and solely for the limited purposes of this action only, Sandoz does not contest subject matter jurisdiction as to Plaintiff's infringement allegations against Sandoz under 35 U.S.C. § 271(e)(2)(A) in this matter. Sandoz denies that subject matter

jurisdiction is proper for any claims asserted against Sandoz Inc. under 35 U.S.C. § 271(a), (b), or (c). Sandoz denies the remaining allegations of Paragraph 9.

Complaint ¶ 10: Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Sandoz.

Response: Paragraph 10 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey in this matter.

Complaint ¶ 11: Upon information and belief, Sandoz has a principal place of business in New Jersey, and is in the business of, among other things, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic versions of branded pharmaceutical products throughout the United States, including in New Jersey, through its own actions and/or through the actions of its agents and subsidiaries, from which Sandoz derives a substantial portion of its revenue.

Response: Paragraph 11 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, does not contest personal jurisdiction in the District of New Jersey in this matter.

Complaint ¶ 12: Upon information and belief, Sandoz is registered to do business in New Jersey under Entity Identification Number 0100097265 and is registered with the New Jersey Department of Health as a drug manufacturer and wholesaler under Registration Number 5003732.

Response: Paragraph 12 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey in this matter.

Complaint ¶ 13: Upon information and belief, Sandoz, through its own actions and/or through the actions of its agents and subsidiaries, has engaged in the research and development, and the preparation and filing, of Sandoz's ANDA; continues to engage in seeking FDA approval of Sandoz's ANDA; intends to engage in the commercial manufacture, marketing, offer for sale, sale, or importation of Sandoz's ANDA Product throughout the United States, including in New Jersey; and stands to benefit from the approval of Sandoz's ANDA.

Response: Paragraph 13 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey in this matter.

Complaint ¶ 14: Upon information and belief, Sandoz, through its own actions and/or through the actions of its agents and subsidiaries, prepared and submitted Sandoz's ANDA with certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certifications").

Response: Paragraph 14 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey in this matter. Except as expressly admitted, Sandoz denies the remaining allegations of Paragraph 14.

Complaint ¶ 15: Upon information and belief, upon FDA approval of Sandoz's ANDA, Sandoz will market, offer to sell, sell, or distribute Sandoz's ANDA Product throughout the United States, including in New Jersey, consistently with Sandoz's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Sandoz regularly does business in New Jersey, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. Upon information and belief, Sandoz's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. Upon information and belief, Sandoz's ANDA Product will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and/or used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of the Patents-in-Suit in the event that Sandoz's ANDA Product is approved before the Patents-in-Suit expire.

Response: Paragraph 15 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted Sandoz's ANDA to FDA seeking approval of Sandoz's ANDA Product. Sandoz further admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 15.

Complaint ¶ 16: Upon information and belief, Sandoz derives substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and which are manufactured by Sandoz and/or for which Sandoz is the named applicant on approved ANDAs. Upon information and belief, various products for which Sandoz is the named applicant on approved ANDAs are available at retail pharmacies in New Jersey.

Response: Paragraph 16 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 16.

Complaint ¶ 17: Sandoz is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Sandoz is a corporation with a principal place of business in New Jersey, is registered to do business in New Jersey, and has appointed a registered agent for service of process in New Jersey. It therefore has consented to general jurisdiction in New Jersey. In addition, upon information and belief, Sandoz develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

Response: Paragraph 16 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey.

Complaint ¶ 18: This Court also has personal jurisdiction over Sandoz because, among other things, upon information and belief: (1) Sandoz filed Sandoz's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product in the United States, including in New Jersey; and (2) upon approval of Sandoz's ANDA, Sandoz will directly, or indirectly through subsidiaries, intermediaries, distributors, retailers, or others, market, distribute, offer for sale, sell, and/or import Sandoz's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Sandoz's ANDA Product in New Jersey. Upon information and belief, upon approval of Sandoz's ANDA, Sandoz's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

Response: Paragraph 18 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted Sandoz's ANDA to FDA seeking approval of Sandoz's ANDA Product. Sandoz further admits that solely for the limited purposes

of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 18.

Complaint ¶ 19: This Court also has personal jurisdiction over Sandoz because Sandoz has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiff, which manufactures CAPLYTA® drug products for sale and use throughout the United States, including in New Jersey. As a result, the consequences of Sandoz's actions were, and will be, suffered in New Jersey. Sandoz knew or should have known that the consequences of its actions were, and will be, suffered in New Jersey. It was reasonably foreseeable that Sandoz would be sued in New Jersey, where Sandoz is located. Upon information and belief, Sandoz's actions will injure Plaintiff by displacing at least some, if not all, of Plaintiff's sales of CAPLYTA® drug products in New Jersey, as well as resulting in price erosion and loss of goodwill with the purchasers and distributors of CAPLYTA® drug products in New Jersey.

Response: Paragraph 19 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted Sandoz's ANDA to FDA seeking approval of Sandoz's ANDA Product. Sandoz further admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 19.

Complaint ¶ 20: Sandoz is also subject to personal jurisdiction in New Jersey because it (1) engages in patent litigation concerning Sandoz's generic versions of branded pharmaceutical products in this District, (2) does not contest personal jurisdiction in this District, and (3) purposefully avails itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Intra-Cellular Therapies, Inc. v. Sandoz Inc.*, No. 3-24-cv-04327, ECF No. 10 (D.N.J. June 10, 2024); *Astellas Pharma Inc. v. Sandoz, Inc.*, No. 23-cv-01214, ECF No. 17 (D.N.J. May 1, 2023); *Aragon Pharms., Inc. v. Sandoz Inc.*, No. 22-cv-03044, ECF No. 23 (D.N.J. Aug. 1, 2022).

Response: Paragraph 19 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest personal jurisdiction in the District of New Jersey.

Complaint ¶ 21: For the above reasons, it would not be unfair or unreasonable for Sandoz to litigate this action in this District, and the Court has personal jurisdiction over Sandoz.

Response: Paragraph 21 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action

only, Sandoz does not contest personal jurisdiction in the District of New Jersey. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 21.

Venue

Complaint ¶ 22: Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 23: Venue is proper in this district under 28 U.S.C. § 1391, at least because, upon information and belief, Sandoz resides in this district and a substantial part of the events and injury giving rise to Plaintiff's claims has and continues to occur in this district.

Response: Paragraph 23 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest venue in the District of New Jersey.

Complaint ¶ 24: Venue is proper in this district under 28 U.S.C. § 1400(b), at least because, upon information and belief, Sandoz has a principal place of business in New Jersey and has committed acts of infringement in New Jersey. Upon information and belief, among other things, (1) Sandoz prepared and/or submitted Sandoz's ANDA with Paragraph IV certifications in New Jersey, where Sandoz is located; and (2) upon approval of Sandoz's ANDA, Sandoz will market, distribute, offer for sale, sell, and/or import Sandoz's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Sandoz's ANDA Product in New Jersey.

Response: Paragraph 24 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest venue in the District of New Jersey. Sandoz further admits that it submitted Sandoz's ANDA to FDA seeking approval of Sandoz's ANDA Product. Sandoz further admits that it prepared and submitted Sandoz's ANDA No. 218938 to FDA with certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 24.

Complaint ¶ 25: Venue is proper in this district as to Sandoz because Sandoz (1) engages in patent litigation concerning Sandoz's generic versions of branded pharmaceutical products in this District, and (2) does not contest that venue is proper in this district. *See, e.g.*, *Intra-Cellular Therapies, Inc. v. Sandoz Inc.*, No. 3-24-cv-04327, ECF No. 10 (D.N.J. June 10,

2024); *Astellas Pharma Inc. v. Sandoz, Inc.*, No. 23-cv-01214, ECF No. 17 (D.N.J. May 1, 2023); *Aragon Pharms., Inc. v. Sandoz Inc.*, No. 22-cv-03044, ECF No. 23 (D.N.J. Aug. 1, 2022).

Response: Paragraph 25 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that solely for the limited purposes of this action only, Sandoz does not contest venue in the District of New Jersey.

Factual Background

Complaint ¶ 26: Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 27: CAPLYTA®, which contains lumateperone, is approved for the treatment of schizophrenia in adults, as well as depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate.

Response: Sandoz admits that pursuant to the June 2023 FDA approved label packaging insert for CAPLYTA®, "CAPLYTA is an atypical antipsychotic indicated for the treatment of: schizophrenia in adults and depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate." Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 27.

Complaint ¶ 28: In Sandoz's Notice Letter, Sandoz stated that the subject of Sandoz's ANDA is lumateperone capsules, 10.5 mg, 21 mg, and 42 mg. In Sandoz's Notice Letter, Sandoz stated that Sandoz's ANDA was submitted under 21 U.S.C. § 355(j)(1) & (2)(a) and contended that Sandoz's ANDA contains bioavailability and/or bioequivalence studies for Sandoz's ANDA Product. Upon information and belief, Sandoz's ANDA Product is a generic version of CAPLYTA®.

Response: Paragraph 28 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA with the FDA pursuant to 21 U.S.C. § 355(j) & (2)(a) seeking approval of Sandoz's ANDA Product and states that

Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 28.

Complaint ¶ 29: In Sandoz's Notice Letter, Sandoz stated that it had submitted Paragraph IV certifications to the FDA alleging that the '077 patent, '258 patent, '995 patent, '061 patent, '227 patent, '867 patent, '938 patent, '345 patent, '009 patent, '951 patent, '084 patent, '842 patent, '419 patent, '348 patent, RE '825 patent, and RE '839 patent are invalid, unenforceable, and/or not infringed, and that Sandoz is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product prior to the expiration of those patents.

Response: Paragraph 29 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted its ANDA to FDA seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA and Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 29.

Complaint ¶ 30: The purpose of Sandoz's submission of Sandoz's ANDA was to obtain, *inter alia*, approval under the Federal Food, Drug, and Cosmetic Act (the "FDCA") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit. On information and belief, Sandoz intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the Patents-in-Suit.

Response: Paragraph 30 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it submitted Sandoz's ANDA to FDA seeking approval of Sandoz's ANDA Product and states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 30.

Count I—Infringement of the '617 Patent

Complaint ¶ 31: Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 32: The '617 patent, entitled "Methods of Treating Acute Depression and/or Acute Anxiety" (attached as Exhibit A), was duly and legally issued on May 14, 2024.

Response: Paragraph 32 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '617 patent is titled "Methods of Treating Acute Depression and/or Acute Anxiety" and that the face of the '617 patent identifies December May 14, 2024 as the "Date of Patent." Sandoz admits that Exhibit A to Plaintiff's Complaint purports to be a copy of the '617 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 32.

Complaint ¶ 33: The inventors named on the '617 patent are Gretchen Snyder, Robert Davis, and Lawrence Wennogle.

Response: Paragraph 33 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '617 patent identifies "Gretchen Snyder," "Robert Davis," and "Lawrence P. Wennogle" as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 33 and therefore denies them.

Complaint ¶ 34: Plaintiff is the owner and assignee of the '617 patent.

Response: Paragraph 34 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '617 patent identifies "INTRACELLULAR THERAPIES, INC." as the assignee. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 34 and therefore denies them.

Complaint ¶ 35: CAPLYTA® is covered by one or more claims of the '617 patent, which has been listed in connection with CAPLYTA® in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the Orange Book").

Response: Paragraph 35 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA®

identifies the '617 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations in Paragraph 35.

Complaint ¶ 36: In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the '617 patent.

Response: Paragraph 36 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 36.

Complaint ¶ 37: According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

Response: Paragraph 37 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter says "Pursuant to 21 C.F.R. § 314.95(c)(5), the active ingredient in the proposed drug product is lumateperone; the strength of the proposed drug product is 10.5 mg lumateperone, 21 mg lumateperone, and 42 mg lumateperone." Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 37.

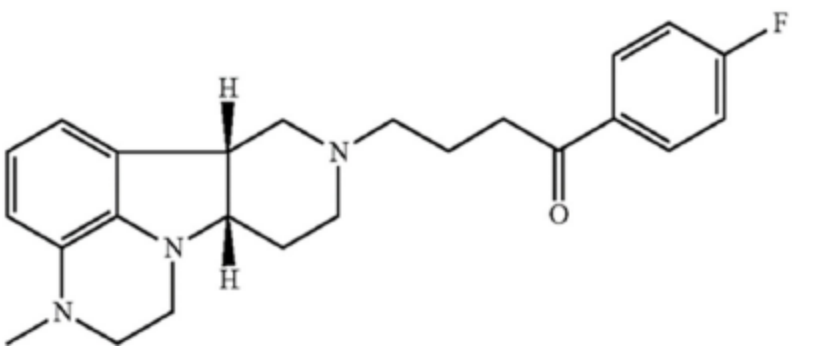
Complaint ¶ 38: Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe one or more claims of the '617 patent.

Response: Paragraph 38 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 39: As an example, claim 1 of the '617 patent recites:

> A method of treating acute depression and/or acute anxiety, comprising administering to a patient in need thereof, a therapeutically effective amount of a Compound of Formula I:

Formula I

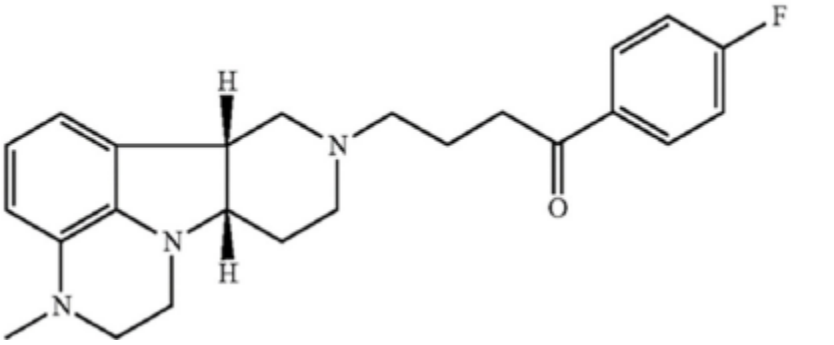


in free, or pharmaceutically acceptable salt form.

Response: Paragraph 43 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '617 patent claim 1 recites the following:

> A method of treating acute depression and/or acute anxiety, comprising administering to a patient in need thereof, a therapeutically effective amount of a Compound of Formula I:

Formula I



Complaint ¶ 40: Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed label would involve treating acute depression and/or acute anxiety, including by administering to the patient in need thereof a free or pharmaceutically acceptable salt form of a Formula I compound (which is lumateperone) in a therapeutically effective dose, as recited in claim 1.

Response: Paragraph 40 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that its proposed label speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 40.

Complaint ¶ 41: Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed product labeling would infringe one or more claims of the '617 patent, literally or under the doctrine of equivalents.

Response: Paragraph 41 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 42: Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '617 patent was an act of infringement of the '617 patent under 35 U.S.C. § 271(e)(2)(A).

Response: Paragraph 42 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 42.

Complaint ¶ 43: Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 43 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 43.

Complaint ¶ 44: Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '617 patent.

Response: Paragraph 44 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 45: Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '617 patent.

Response: Paragraph 45 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 46: Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '617 patent when Sandoz's ANDA is approved, and plans and

intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '617 patent and specific intent to infringe that patent.

Response: Paragraph 46 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 47: Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '617 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '617 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 47 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 48: Notwithstanding Sandoz's knowledge of the claims of the '617 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '617 patent.

Response: Paragraph 48 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 49: The foregoing actions by Sandoz constitute and/or will constitute infringement of the '617 patent; active inducement of infringement of the '617 patent; and/or contribution to the infringement by others of the '617 patent.

Response: Paragraph 49 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 50: Upon information and belief, Sandoz has acted with full knowledge of the '617 patent and without a reasonable basis for believing that it would not be liable for infringement of the '617 patent; active inducement of infringement of the '617 patent; and/or contribution to the infringement by others of the '617 patent.

Response: Paragraph 50 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 51: Plaintiff will be substantially and irreparably damaged by infringement of the '617 patent.

Response: Paragraph 51 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 52: Unless Sandoz is enjoined from infringing the '617 patent, actively inducing infringement of the '617 patent, and contributing to the infringement by others of the '617 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Response: Paragraph 56 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count II—Declaratory Judgment of Infringement of the '617 Patent

Complaint ¶ 53: Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 54: The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '617 patent, and/or the validity of the '617 patent.

Response: Paragraph 54 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '617 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 54.

Complaint ¶ 55: The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '617 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '617 patent, and that the claims of the '617 patent are not invalid.

Response: Paragraph 55 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count III—Infringement of the '459 Patent

Complaint ¶ 56: Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 57: The '459 patent, entitled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" (attached as Exhibit B), was duly and legally issued on August 27, 2024.

Response: Paragraph 57 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '459 patent is titled "Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-Tosylate" and that the face of the '459 patent identifies August 27, 2024 as the "Date of Patent." Sandoz admits that Exhibit B to Plaintiff's Complaint purports to be a copy of the '459 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 57.

Complaint ¶ 58: The inventors named on the '459 patent are Peng Li and Robert Davis.

Response: Paragraph 58 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '459 patent identifies "Peng Li" and "Robert Davis" as the inventors. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 58 and therefore denies them.

Complaint ¶ 59: Plaintiff is the owner and assignee of the '459 patent.

Response: Paragraph 59 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the face of the '459 patent identifies "INTRACELLULAR THERAPIES, INC." as the assignee. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 59 and therefore denies them.

Complaint ¶ 60: CAPLYTA® is covered by one or more claims of the '459 patent, which will be listed in connection with CAPLYTA® in the Orange Book.

Response: Paragraph 60 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that FDA's Orange Book entry for CAPLYTA® identifies the '459 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 60.

Complaint ¶ 61: In Sandoz's Notice Letter, Sandoz notified Plaintiff of the submission of Sandoz's ANDA to the FDA. The purpose of this submission was to obtain, among other things, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product prior to the expiration of the '459 patent.

Response: Paragraph 61 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that it notified Plaintiff, via Sandoz's Notice Letter, of the submission of Sandoz's ANDA to the FDA. Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 61.

Complaint ¶ 62: According to Sandoz's Notice Letter, Sandoz's ANDA Product contains lumateperone.

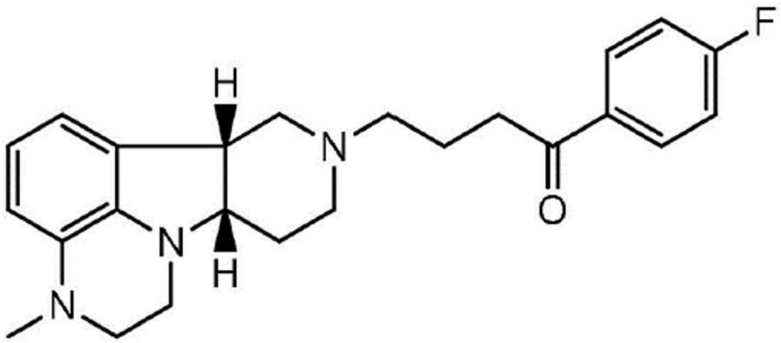
Response: Paragraph 62 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's Notice Letter speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 62.

Complaint ¶ 63: Upon information and belief, the use of Sandoz's ANDA Product in accordance with and as directed by Sandoz's proposed labeling for that product would infringe one or more claims of the '459 patent.

Response: Paragraph 63 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 64: As an example, claim 1 of the '459 patent recites:

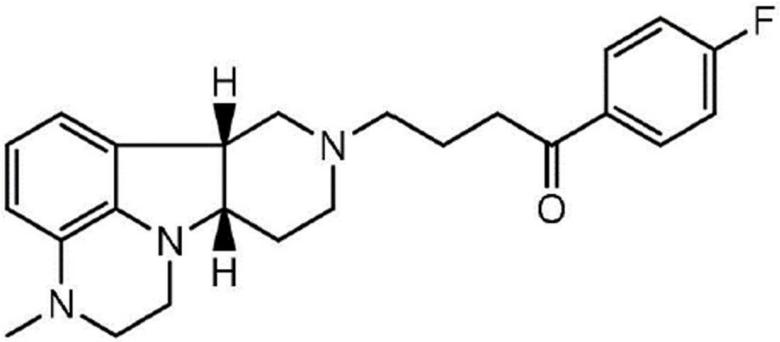
> A pharmaceutical capsule for oral administration, comprising lumateperone:



in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form, wherein the capsule comprises the lumateperone mono-tosylate in an amount of about 60 mg lumateperone mono-tosylate in solid crystal form, and wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, and one or more pharmaceutically acceptable diluents or carriers comprising one or more of (a) diluent/filler, (b) binder, (c) disintegrant, (d) lubricant, or (e) a glidant, and wherein administration of an oral dose of a single capsule under fasting conditions provides a maximal plasma concentration of lumateperone of 15-55 ng/mL, and/or a time to maximal plasma concentration of lumateperone of 0.7 to 1.5 hours, and/or an area under the plasma concentration curve (AUC) extrapolated to infinity (AUC(0-inf)) of 51 to 135 hours-ng/mL.

Response: Paragraph 64 states legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that the '459 patent recites the following for claim 1:

A pharmaceutical capsule for oral administration, comprising lumateperone:



> in mono-tosylate salt form, wherein the lumateperone mono-tosylate is in solid crystal form, wherein the capsule comprises the lumateperone mono-tosylate in an amount of about 60 mg lumateperone mono-tosylate in solid crystal form, and wherein the capsule comprises a blend of 10 to 30% by weight of lumateperone mono-tosylate in solid crystal form, and one or more pharmaceutically acceptable diluents or carriers comprising one or more of (a) diluent/filler, (b) binder, (c) disintegrant, (d) lubricant, or (e) a glidant, and wherein administration of an oral dose of a single capsule under fasting conditions provides a maximal plasma concentration of lumateperone of 15-55 ng/mL, and/or a time to maximal plasma concentration of lumateperone of 0.7 to 1.5 hours, and/or an area under the plasma concentration curve (AUC) extrapolated to infinity (AUC(0-inf)) of 51 to 135 hours-ng/mL.

Complaint ¶ 65: Upon information and belief, Sandoz's ANDA Product is a pharmaceutical capsule for oral administration comprising lumateperone mono-tosylate in solid crystal form in a blend with one or more of the specific diluents or carriers in the specific amounts recited in claim 1. Upon information and belief, administration of an oral dose of a single capsule of Sandoz's ANDA Product under fasting conditions will provide a maximal plasma concentration of lumateperone and/or time to maximal plasma concentration of lumateperone and/or area under the plasma concentration curve extrapolated to infinity within the specific ranges recited in claim 1.

Response: Paragraph 65 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA, which describes its ANDA Product, speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 65.

Complaint ¶ 66: Upon information and belief, Sandoz's ANDA Product infringes one or more claims of the '459 patent, literally or under the doctrine of equivalents.

Response: Paragraph 66 states legal conclusions to which no response is required. To the extent a response is required, denied

Complaint ¶ 67: Sandoz's submission of Sandoz's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product before the expiration of the '459 patent was an act of infringement of the '459 patent under 35 U.S.C. § 271(e)(2)(A).

Response: Paragraph 67 states legal conclusions to which no response is required. To the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 67.

Complaint ¶ 68: Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sandoz's ANDA Product immediately and imminently upon approval of its ANDA.

Response: Paragraph 68 states legal conclusions to which no response is required, to the extent a response is required, Sandoz states that Sandoz's ANDA speaks for itself. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 68.

Complaint ¶ 69: Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more claims of the '459 patent.

Response: Paragraph 69 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 70: Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product in accordance with and as directed by its proposed product labeling would infringe one or more claims of the '459 patent.

Response: Paragraph 70 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 71: Upon information and belief, Sandoz plans and intends to, and will, actively induce infringement of the '459 patent when Sandoz's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Sandoz's activities will be done with knowledge of the '459 patent and specific intent to infringe that patent.

Response: Paragraph 71 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 72: Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '459 patent, that Sandoz's ANDA Product is not a staple article or commodity of commerce, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Sandoz plans and intends to, and will, contribute to infringement of the '459 patent immediately and imminently upon approval of Sandoz's ANDA.

Response: Paragraph 72 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 73: Notwithstanding Sandoz's knowledge of the claims of the '459 patent, Sandoz has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Sandoz's ANDA Product with its product labeling following FDA approval of Sandoz's ANDA prior to the expiration of the '459 patent.

Response: Paragraph 73 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 74: The foregoing actions by Sandoz constitute and/or will constitute infringement of the '459 patent; active inducement of infringement of the '459 patent; and/or contribution to the infringement by others of the '459 patent.

Response: Paragraph 74 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 75: Upon information and belief, Sandoz has acted with full knowledge of the '459 patent and without a reasonable basis for believing that it would not be liable for infringement of the '459 patent; active inducement of infringement of the '459 patent; and/or contribution to the infringement by others of the '459 patent.

Response: Paragraph 75 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 76: Plaintiff will be substantially and irreparably damaged by infringement of the '459 patent.

Response: Paragraph 76 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 77: Unless Sandoz is enjoined from infringing the '459 patent, actively inducing infringement of the '459 patent, and contributing to the infringement by others of the '459 patent, Plaintiff will suffer irreparable injury. Plaintiff has no adequate remedy at law.

Response: Paragraph 77 states legal conclusions to which no response is required. To the extent a response is required, denied.

Count IV—Declaratory Judgment of Infringement of the '459 Patent

Complaint ¶ 78: Plaintiff incorporates each of the preceding paragraphs as if fully set forth herein.

Response: Sandoz incorporates by reference fully herein each preceding paragraph.

Complaint ¶ 79: The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiff on the one hand and Sandoz on the other regarding Sandoz's infringement, active inducement of infringement, contribution to the infringement by others of the '459 patent, and/or the validity of the '459 patent.

Response: Paragraph 79 contains legal conclusions to which no response is required. To the extent a response is required, Sandoz admits that because of Plaintiff's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '459 patent. Except as otherwise expressly admitted, Sandoz denies the remaining allegations of Paragraph 79.

Complaint ¶ 80: The Court should declare that the commercial manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product with its proposed labeling, or any other Sandoz drug product that is covered by or whose use is covered by the '459 patent, will infringe, induce infringement of, and contribute to the infringement by others of the '459 patent, and that the claims of the '459 patent are not invalid.

Response: Paragraph 80 states legal conclusions to which no response is required. To the extent a response is required, denied.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

(a) A judgment that the Patents-in-Suit have been infringed under 35 U.S.C. § 271(e)(2) by Sandoz's submission to the FDA of Sandoz's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Sandoz's ANDA Product, or any other drug product that infringes or the use of which infringes the Patents-in-Suit, be not earlier than

the expiration dates of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Sandoz, and all persons acting in concert with Sandoz, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's ANDA Product, or any other drug product covered by or whose use is covered by the Patents-in-Suit, prior to the expiration of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale, or importation of Sandoz's ANDA Product, or any other drug product covered by or whose use is covered by the Patents-in-Suit, prior to the expiration of said patents, will infringe, induce the infringement of, and contribute to infringement by others of said patents;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

RESPONSE TO REQUEST FOR RELIEF

Sandoz denies all allegations not specifically admitted herein, and further denies that Plaintiff is entitled to the judgment and relief requested in paragraphs (a)-(g) of its Complaint or to any relief whatsoever.

AFFIRMATIVE DEFENSES

Without any admissions as to burden of proof, and expressly reserving its right to assert additional defenses, Sandoz states the following affirmative defenses:

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

Plaintiff fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE
(Non-Infringement)

The manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product that is the subject of ANDA No. 218938 has not and will not infringe directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner, any valid and enforceable claim of the '617 patent or the '459 patent.

THIRD AFFIRMATIVE DEFENSE
(Invalidity)

The claims of the '617 patent and the '459 patents are invalid for failure to satisfy one or more of the conditions for patentability under the patent laws of the United States, including without limitation, 35 U.S.C. §§ 101, 102, 103, 112, 251, and/or 282(c), *et seq.*, and/or for obviousness-type double patenting, and/or for any other judicially-created and/or non-statutory basis for invalidity.

FOURTH AFFIRMATIVE DEFENSE
(No Costs)

Plaintiff is barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

FIFTH AFFIRMATIVE DEFENSE
(No Injunctive Relief)

Plaintiff may not seek injunctive relief against Sandoz, including under 35 U.S.C. §§ 271(3)(4)(B) and/or 283, because Plaintiff's alleged damages are not immediate or irreparable, and Plaintiff therefore has an adequate remedy at law.

SIXTH AFFIRMATIVE DEFENSE
(No Exceptional Case)

Sandoz's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

SEVENTH AFFIRMATIVE DEFENSE
(Equitable Defenses)

Sandoz reserves the right to amend its Answer to include equitable defenses, such as inequitable conduct, unclean hands, laches, estoppel and/or patent misuse, if information obtained in discovery provides support for such a defense.

EIGHTH AFFIRMATIVE DEFENSE
(Reservation of Rights)

Sandoz reserves the right to add or amend its Affirmative Defenses with additional affirmative defenses that discovery may yield, including unenforceability.

* * *

COUNTERCLAIMS

In further response to the Complaint, Defendant/Counterclaim-Plaintiff Sandoz Inc. ("Sandoz" or "Counterclaim-Plaintiff"), without admitting any of the allegations of Plaintiff other than as expressly admitted herein, and without prejudice of the rights of Sandoz to plead additional Counterclaims as the facts of the matter warrant, alleges as follows:

THE PARTIES

1. Sandoz Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 100 College Road West, Princeton, NJ 08540.

2. Counterclaim-Defendant Intra-Cellular Therapies, Inc. ("Intra-Cellular Therapies," or "Counterclaim-Defendant") has averred that it is a corporation organized and existing under the laws of the State of Delaware, with its corporate headquarters at 430 East 29th Street, Suite 900, New York, NY 10016.

JURISDICTION AND VENUE

3. This is a declaratory judgment action arising under the patent laws of the United States, Title 35, United States Code.

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. The requested relief is authorized by the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court has personal jurisdiction over Intra-Cellular Therapies because, inter alia, Intra-Cellular Therapies subjected itself to the jurisdiction of this Court by filing this action here; Intra-Cellular Therapies has averred that it is a corporation organized and existing under the laws of the State of Delaware; and upon information and belief, either directly or through agents, Intra-Cellular Therapies transacts business in, and derives substantial revenue from, the State of New Jersey.

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

8. Because of Counterclaim-Defendant's Complaint against Sandoz, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of United States Patent Nos. 11,980,617 ("the '617 patent") and 12,070,459 ("the '459 patent"). These patents are referred to collectively herein as the "Patents-in-Suit."

FACTUAL BACKGROUND

9. According to the United States Food and Drug Administration ("FDA") publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), Intra-Cellular Therapies is the holder of New Drug Application ("NDA") No. 209500, under which FDA granted approval for lumateperone capsules, 10.5 mg, 21 mg, and 42 mg, marketed in the United States as CAPLYTA® ("CAPLYTA® ").

10. Under 21 U.S.C. §§ 355(b)(1)(A)(viii), (c)(2), and 21 C.F.R. § 314.53(b), NDA holders "shall submit" to FDA:

> the patent number and expiration date of each patent for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug, and that—
>
> > (I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or
> >
> > (II) claims a method of using such drug for which approval is sought or has been granted in the application.

Pursuant to 21 C.F.R. § 314.53(e), "FDA will publish in the [Orange Book] the patent number and expiration date of each patent that is required to be, and is, submitted to FDA by an applicant, and for each method-of-use patent, the description of the method of use claimed by the patent . . . ."

11. The Orange Book lists the '617 patent in association with NDA No. 209500 for CAPLYTA® 10.5 mg, 21 mg, and 42 mg capsules.

12. The Orange Book lists the '459 patent in association with NDA No. 209500 for CAPLYTA® 42 mg capsules.

13. The faces of the Patents-in-Suit identify "INTRA-CELLULAR THERAPIES, INC." as the assignee.

14. Intra-Cellular has averred that it is the assignee and owner of each of the Patents-in-Suit.

15. Intra-Cellular has also averred that it owns all rights, title, and interest in and to each of the Patents-in-Suit.

16. The ’617 patent is titled “Methods of Treating Acute Depression and/or Acute Anxiety.” The face of the ’617 patent identifies May 14, 2024 as the “Date of Patent.”

17. The ’459 patent is titled “Pharmaceutical Capsule Compositions Comprising Lumateperone Mono-tosylate.” The face of the ’459 patent identifies August 27, 2024 as the “Date of Patent.”

18. Upon information and belief, Intra-Cellular caused the ’617 patent and the ’459 patent to be listed in the Orange Book in connection with NDA No. 209500.

19. Sandoz submitted Abbreviated New Drug Application (“ANDA”) No. 218938 (“Sandoz’s ANDA”) to the FDA seeking approval for lumateperone capsules, 10.5 mg, 21 mg, and 42 mg (“Sandoz’s ANDA Product”).

20. Sandoz’s ANDA includes a Paragraph IV certification under 21 U.S.C. § 355(b)(2)(A)(iv) (“Paragraph IV certification”) with respect to the ’629 Patent, the RE’221 Patent, the ’080 Patent, the ’459 Patent, the ’164 Patent, the ’400 Patent, the ’923 Patent, the ’924 Patent, the ’584 Patent, the ’697 Patent, the ’624 Patent, the ’425 Patent, the ’069 Patent, and the ’627 Patent, which were listed in the Orange Book prior to Sandoz filing its ANDA. The Patents-in-Suit were listed in the Orange Book after Sandoz filed its ANDA.

21. Counterclaim-Defendant initiated the present litigation by filing a complaint against Sandoz Inc. on August 29, 2024 alleging infringement of the Patens-in-Suit.

22. Counterclaim-Defendant has alleged in the present action that Sandoz has infringed and will infringe the Patents-in-Suit by filing Sandoz's ANDA with the FDA and/or by manufacturing, using, offering for sale, selling, or importing Sandoz's ANDA Product.

23. As a consequence of the foregoing, there is an actual and justiciable controversy between Sandoz Inc. and Counterclaim-Defendant as to whether the claims of the Patens-in-Suit are invalid, and whether those claims are being infringed or will be infringed by Sandoz's ANDA or by the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product.

COUNT 1
Declaratory Judgment of Non-Infringement of the '617 Patent

24. Sandoz Inc. realleges and incorporates by reference the allegations of Paragraphs 1-23 as though fully set forth herein.

25. A present, genuine, and justiciable controversy exists between Sandoz and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would infringe any valid or enforceable claim of the '617 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

26. The manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would not infringe any valid or enforceable claim of the '617 patent, either directly or indirectly.

27. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the '617 patent.

COUNT 2
Declaratory Judgment of Non-Infringement of the ’459 Patent

28. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–27 as though fully set forth herein.

29. A present, genuine, and justiciable controversy exists between Sandoz Inc. and Counterclaim-Defendant regarding, inter alia, whether the manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product would infringe any valid or enforceable claim of the ’459 patent, either directly or indirectly, that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

30. The manufacture, use, offer for sale, sale, and/or importation of Sandoz’s ANDA Product would not infringe any valid or enforceable claim of the ’459 patent, either directly or indirectly.

31. Sandoz is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, one or more valid or enforceable claims of the ’459 patent.

COUNT 3
Declaratory Judgment of Invalidity of the ’617 Patent

32. Sandoz realleges and incorporates by reference the allegations of Paragraphs 1–31 as though fully set forth herein.

33. A present, genuine, and justiciable controversy exists between Sandoz Inc. and Counterclaim-Defendant regarding, inter alia, the invalidity of the ’617 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

34. The claims of the ’617 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112,

the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

35. By way of non-limiting examples, one or more claims of the ’617 patent are invalid as obvious under 35 U.S.C. § 103 in view of prior art to the ’617 patent. Non-limiting examples of such art include U.S. Patent No. 8,598,119 (“Mates”) and U.S. Patent Publication Number 2016/0310502 (“Vanover”), in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

36. Sandoz is entitled to a judicial declaration that the claims of the ’617 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting.

COUNT 4
Declaratory Judgment of Invalidity of the ’459 Patent

37. Sandoz Inc. realleges and incorporates by reference the allegations of Paragraphs 1–36 as though fully set forth herein.

38. A present, genuine, and justiciable controversy exists between Sandoz Inc. and Counterclaim-Defendant regarding, inter alia, the invalidity of the ’459 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

39. The claims of the ’459 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 100 et seq., including but not limited to, §§ 101, 102, 103, and/or 112, the doctrine of obviousness-type double-patenting, and/or for judicially-created doctrines and/or non-statutory bases of invalidity or unenforceability.

40. By way of non-limiting examples, one or more claims of the ’459 patent are invalid as anticipated under 35 U.S.C. § 102 and/or obvious under 35 U.S.C. § 103 in view of prior art to

the ’459 patent. Non-limiting examples of such art include International Patent Application Numbers 2015/085004 (“Vanover I”) and 2009/114181 (“Wennogle”), in addition to the knowledge of a person of ordinary skill in the art and the state of the art.

41. Sandoz is entitled to a judicial declaration that the claims of the ’459 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code and/or for any other judicially-created and/or non-statutory bases for invalidity or unenforceability, including double-patenting.

PRAYER FOR RELIEF

WHEREFORE, Sandoz respectfully prays for judgment in its favor and against Counterclaim-Defendant:

a) Declaring that the filing of Sandoz’s ANDA did not infringe any valid and enforceable claim of the Patents-in-Suit;

b) Declaring that the manufacture, use, sale, offer for sale, and/or importation of Sandoz’s ANDA Product described in Sandoz’s ANDA has not infringed, does not infringe, and would not–if made, used, sold, offered for sale, imported, or marketed–infringe, either directly or indirectly, any valid and enforceable claim of the Patents-in-Suit either literally or under the doctrine of equivalents;

c) Declaring that the claims of the ’617 patent are invalid;

d) Declaring that the claims of the ’459 patent are invalid;

e) Ordering that the Complaint be dismissed with prejudice and judgment entered in favor of Sandoz Inc.;

f) Denying Plaintiff/Counterclaim-Defendant any of the relief requested in the Complaint;

g) Declaring this case exceptional in favor of Sandoz Inc. pursuant to 35 U.S.C. § 285;

h) Awarding costs and attorneys' fees to Sandoz Inc.; and

i) Awarding Sandoz such other and further relief the Court may deem just and proper.

LOCAL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in this action is related to the following actions: *Intra-Cellular Therapies, Inc. v. Aurobindo Pharma Ltd. et al*, 3:24-cv-04264 (consolidated), pending before the United States District Court for the District of New Jersey, in which Plaintiff asserted claims of patent infringement against, inter alia, Defendant in connection with Defendant's submission of ANDA No. 218938; *Intra-Cellular Therapies, Inc. v. Sandoz Inc*., 3:24-cv-04327-MAS-JBD, before the United States District Court for the District of New Jersey, which has been consolidated with Case No. 3:24-cv-04264-MAS-JBD and in which Plaintiff asserted claims of patent infringement against Defendant in connection with Defendant's submission of ANDA No. 218938.

LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

Dated: November 12, 2024

Respectfully submitted,

s/Eric I. Abraham

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CERTIFICATE OF SERVICE

I, Eric I. Abraham, of full age, hereby certify that on November 12, 2024, Defendant, Sandoz Inc.'s, Answer was filed via electronic filing system. A copy of same was served via e-filing upon counsel of record for Plaintiff.

By: *s/Eric I. Abraham*
Eric I. Abraham

Dated: November 12, 2024